ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 50 micrograms powder and solvent for solution for injection – 1 pen, 1 injection needle and 2 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 50 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 50 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

1 pen, 1 injection needle and 2 cleansing swabs
50 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/031

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 50 micrograms powder and solvent for solution for injection – 4 pens, 4 injection needles and 8 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 50 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 50 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

4 pens, 4 injection needles and 8 cleansing swabs
50 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/032

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 50 micrograms powder and solvent for solution for injection – 6 pens, 6 injection needles and 12 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 50 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 50 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

6 pens, 6 injection needles and 12 cleansing swabs
50 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/033

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 50 micrograms powder and solvent for solution for injection – 12 pens, 12 injection needles and 24 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 50 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 50 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

12 pens, 12 injection needles and 24 cleansing swabs
50 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/034

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PegIntron 50 micrograms powder and solvent for solution for injection

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

PegIntron 50 micrograms powder and solvent for injection
S.C.

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

50 micrograms/0.5 ml

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 80 micrograms powder and solvent for solution for injection – 1 pen, 1 injection needle and 2 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 80 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 80 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

1 pen, 1 injection needle and 2 cleansing swabs
80 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/035

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 80 micrograms powder and solvent for solution for injection – 4 pens, 4 injection needles and 8 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 80 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 80 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

4 pens, 4 injection needles and 8 cleansing swabs
80 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/036

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 80 micrograms powder and solvent for solution for injection – 6 pens, 6 injection needles and 12 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 80 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 80 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

6 pens, 6 injection needles and 12 cleansing swabs
80 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/037

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 80 micrograms powder and solvent for solution for injection – 12 pens, 12 injection needles and 24 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 80 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 80 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

12 pens, 12 injection needles and 24 cleansing swabs
80 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/ 1/00/131/038

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PegIntron 80 micrograms powder and solvent for solution for injection

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

PegIntron 80 micrograms powder and solvent for injection
S.C.

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

80 micrograms/0.5 ml

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 100 micrograms powder and solvent for solution for injection – 1 pen, 1 injection needle and 2 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 100 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 100 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

1 pen, 1 injection needle and 2 cleansing swabs
100 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/039

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 100 micrograms powder and solvent for solution for injection – 4 pens, 4 injection needles and 8 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 100 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 100 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

4 pens, 4 injection needles and 8 cleansing swabs
100 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/040

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 100 micrograms powder and solvent for solution for injection – 6 pens, 6 injection needles and 12 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 100 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 100 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

6 pens, 6 injection needles and 12 cleansing swabs
100 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/041

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 100 micrograms powder and solvent for solution for injection – 12 pens, 12 injection needles and 24 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 100 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 100 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

12 pens, 12 injection needles and 24 cleansing swabs
100 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/042

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PegIntron 100 micrograms powder and solvent for solution for injection

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

PegIntron 100 micrograms powder and solvent for injection
S.C.

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

100 micrograms/0.5 ml

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 120 micrograms powder and solvent for solution for injection – 1 pen, 1 injection needle and 2 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 120 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 120 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

1 pen, 1 injection needle and 2 cleansing swabs
120 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/043

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 120 micrograms powder and solvent for solution for injection – 4 pens, 4 injection needles and 8 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 120 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 120 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

4 pens, 4 injection needles and 8 cleansing swabs
120 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/044

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 120 micrograms powder and solvent for solution for injection – 6 pens, 6 injection needles and 12 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 120 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 120 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

6 pens, 6 injection needles and 12 cleansing swabs
120 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/045

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 120 micrograms powder and solvent for solution for injection – 12 pens, 12 injection needles and 24 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 120 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 120 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

12 pens, 12 injection needles and 24 cleansing swabs
120 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/046

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PegIntron 120 micrograms powder and solvent for solution for injection

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

PegIntron 120 micrograms powder and solvent for injection
S.C.

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

120 micrograms/0.5 ml

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 150 micrograms powder and solvent for solution for injection – 1 pen, 1 injection needle and 2 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 150 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 150 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

1 pen, 1 injection needle and 2 cleansing swabs
150 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/047

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 150 micrograms powder and solvent for solution for injection – 4 pens, 4 injection needles and 8 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 150 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 150 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

4 pens, 4 injection needles and 8 cleansing swabs
150 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/048

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 150 micrograms powder and solvent for solution for injection – 6 pens, 6 injection needles and 12 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 150 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 150 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

6 pens, 6 injection needles and 12 cleansing swabs
150 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/049

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

PegIntron 150 micrograms powder and solvent for solution for injection – 12 pens, 12 injection needles and 24 cleansing swabs.

1. NAME OF THE MEDICINAL PRODUCT

PegIntron 150 micrograms powder and solvent for solution for injection pre-filled pen
peginterferon alfa-2b

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One PegIntron pre-filled pen contains a sufficient amount of peginterferon alfa-2b to provide 150 micrograms in 0.5 ml of peginterferon alfa-2b when reconstituted as recommended.

3. LIST OF EXCIPIENTS

Excipients: disodium phosphate, anhydrous; sodium dihydrogen phosphate dihydrate, sucrose and polysorbate 80. Solvent: water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

12 pens, 12 injection needles and 24 cleansing swabs
150 micrograms/0.5 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store at 2°C – 8°C (in a refrigerator).

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After injection of the dose, discard the pen in an appropriate container.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: SP Europe, 73, rue de Stalle, B-1180 Bruxelles, Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/131/050

13. MANUFACTURER'S BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PegIntron 150 micrograms powder and solvent for solution for injection

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

PegIntron 150 micrograms powder and solvent for injection
S.C.

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

150 micrograms/0.5 ml